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EXAMINER	
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ART UNIT	PAPER NUMBER
3696	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/825,533	HUFFORD ET AL.	
	Examiner	Art Unit	
	MARTIN A. GOTTSCHALK	3696	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-30 and 48-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-30 and 48-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. Claims 4-30 and 48-52 are pending. Claims 4, 5, 8, 14, 16, 24, and 48-52 are amended. Claims 1-3 and 31-47 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/05/2007 has been entered.

Election/Restriction

3. Per SPE James Trammell, pursuant to the interview held on 01/18/08 between Ms. Ester Kepplinger (Applicant's representative) and Mr. Trammell, and recorded in the Interview Summary posted on 01/24/2008, the Requirement for Election/Restriction mailed 07/20/2007 is vacated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4-11, 13-30 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stark et al (US Pat# 6,827,670, hereinafter, Stark) in view of Drazen (US PG Pub# 2002/0120471).

A. As per claims 4-6, 8, 14, 24, 26, 48-52, and exemplary independent claim 16, Stark discloses a method of predicting subject noncompliance during a current clinical trial, comprising the steps of:

(a) providing historical subject compliance data (Stark: col 5, ln 64 to col 6, ln 1; col 7, 57-60, i.e. "historic database" includes "patient compliance information"; col 11,

lns 40-48; Fig. 11, i.e. patient compliance data from the past 10 days is provided to the central computer.);

(b) generating at least one predictive (Stark: col 8, lns 45-57, i.e. the system is designed for prediction) algorithm for predicting subject noncompliance (Stark: col 13, lns 38-39. Note the use of low "compliance track record" as an input to the algorithm which determines if or by how much to adjust the "challenge level," i.e. a subject who has complied poorly in the past would have this history taken into account with respect to future protocol adjustments. Note further that the Examiner considers the "challenge level" to be a type of "compliance threshold," as recited in claim 4) by quantitative analysis of the historical subject compliance data (Stark: col 12, lns 48-63; Fig 14, note the graphic representation which is a type of quantitative analysis.);

(c) translating the at least one predictive algorithm into at least one prediction rule (Stark: col 9, ln 55 to col 10, ln 30; col 13, lns 6-16, i.e. the Examiner considers that the algorithm is translated it into a rule such as, "If the patient has achieved near 100% performance, then the challenge level of the protocol should be increased.");

(d) obtaining subject compliance information (Stark: col 11, lns 40-48; Fig. 11, i.e. compliance data is obtained from the patient; col 13, lns 2-5, reads on, "…level of average compliance.");

(e) comparing the subject compliance information to the at least one prediction rule to determine if action is needed (Stark: col 5, lns 34-36; col 9, ln 55 to col 10, ln 30; col 12, lns 18-39; col 13, lns 2-5); and

(f) prompting action if the step of comparing indicates that action is needed (Stark: : col 9, ln 55 to col 10, ln 30; col 13, lns 13-16, reads on "…algorithm increases the challenge level…").

Steps (a) and (c) above have been amended to distinguish between previous and current clinical trials as follows:

(a) providing historical subject compliance data <u>from a previous clinical trial;</u>

and

(c) translating the at least one predictive algorithm into at least one prediction rule <u>for use during the current clinical trial.</u>

Stark suggests additional uses of the data generated by the system (Stark: col 12, lns 40-42), but fails to explicitly teach use of the system in clinical trials. However, this feature is well known as taught by Drazen. Drazen teaches a system for storing historical patient information for a plurality of patients in a research database (Drazen: [0036]) in order to correlate the historical information to the compliance of a current patient in a treatment program (Drazen: [0051]; Figs 1 and 2). This is used to generate outcome-specific research data for use in a clinical trial (Drazen: [0039]). The system stores all pertinent patient information from each physician-patient encounter so as to track patient compliance and other information. The database can then be queried in the future for this compliance history. Additionally, treatment outcomes are measured to determine if a certain treatment protocol is effective (Drazen: [0054]-[0054]). Note that the "Patient Information Database" (Drazen: Fig 2, item 120) contains the historical information for the plurality of patients, and is the same database where current patient information is entered directly (Drazen: [0040]). Thus current patient information, becomes part of the historical patient information. If the patient information was compliance information from a clinical trial, in a later clinical trial, it would become "historical patient compliance data from a previous clinical trial", as recited in step (a) of the claim. Thus the "Patient Information Database" would be populated with historical subject compliance data from previous clinical trials which could be used in a current clinical trial, such as the use recited in step (c) of the claim.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Stark with the teachings of Drazen concerning the use of historical patient compliance information in clinical trials, with the motivation of efficiently managing a plurality of medical guidelines and identifying patient risk (Drazen: [0009]) in a clinical trial (Drazen: [0039]), thus further leveraging the expertise of the physicians and treatment professionals involved (Stark: col 2, lns 14-18).

B. As per claims 9, 25, and exemplary claim 17, Stark discloses the method of predicting subject noncompliance of claim 16,

wherein said step of providing includes

providing historical protocol data (Stark: col 5, lns 2-4; Fig 9, note that item 107 is labeled “Receive a Protocol” and is connected by arrow 108 coming from the box labeled “Historic Protocols…”)

and

wherein said step of generating includes

quantitative analysis of the historical protocol data (Stark: col 7, lns 41-43).

C. As per claims 10 and exemplary claim 18, Stark discloses the method of determining subject noncompliance of claim 17, wherein the step of providing

employs at least one database containing the historical protocol data (Stark: Fig 9, item 36 and the box labeled "Historic Protocols…" which is shown to be receiving input from item 40; Fig 10, item 36).

D. As per claims 7, 11, 15, 30, and exemplary claim 19, Stark discloses the method of predicting subject noncompliance of claim 16, wherein the step of obtaining includes

the use of a portable electronic device capable of displaying information and receiving and storing input from a user (Stark: col 8, lns 12-30).

E. As per claims 20 and 21-22, Stark discloses the method of predicting subject noncompliance of claim 16 and 20 (for 21 and 22), further comprising the step of

(claim 20) creating an evaluability database adapted to store data related to subject compliance (Stark: col 8, lns 57-63; col 7, ln 63 to col 8, ln 3);

and

(claim 21) providing access to the evaluability database to a sponsor to allow the sponsor to make a determination regarding a subject based on data from the evaluability database (Stark: col 8, lns 57-63; col 7, ln 63 to col 8, ln 3); and

(claim 22) evaluability database is tailored to a condition affecting the subject (For all three claims, Stark: col 8, lns 57-63, whereby sponsor reads on "treatment professional", and the cited "treatment protocol" is considered to be tailored to a condition affecting the patient. See also col 7, ln 63 to col 8, ln 3).

F. As per claims 13 and exemplary claim 23, Stark discloses the method of determining subject noncompliance of claim 16, wherein the step of providing

employs at least one database containing the historical subject compliance data (Stark: Fig 9, item 36 and box labeled "Historic Protocols…" which is shown to be receiving input from item 40; Fig 10, item 36).

G. As per claims 27 and 28, Stark discloses the method of enhancing subject compliance of claim 24, wherein the affirmative action includes

(claim 27) reducing (Stark: col 9, ln 67 to col 10, ln 21);

and

(claim 28) increasing

a number of occurrences of the step of obtaining subject compliance information (For both claims, Stark: col 9, ln 67 to col 10, ln 21. The Examiner considers the "…replicate count…" to be a form of compliance information, and notes it is increased following detection that the previous "…effort or angle objective…" was not being achieved. Since the number of occurrences of a replicate would be increased, so would obtaining this particular form of compliance information. Likewise, if the patient is "…satisfying ahead of schedule, the treatment goal…", logically, the algorithm would move in the opposite direction from the previous example and "…modify the treatment protocol…" such that the "protocol goals may be raised to more challenging levels…". In this scenario, the patient would require an increase in the required effort, and following the logic of the former example, the number of replicates required to comply with the treatment protocol would be reduced.).

H. As per claim 29, Stark discloses the method of enhancing subject compliance of claim 24, wherein the affirmative action includes giving a reward (Stark: col 10, lns 13-

23, reads on "…psychological boost…").

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stark in view of Drazen as applied to claim 8 above, and further in view of Smith (Smith, G., "Statistical Reasoning." Third edition. Ch. 15, pgs. 619-667. Allyn and Bacon, a Division of Simon and Schuster, Inc., Needham Heights, MA. 1991, hereinafter Smith.).

A. As per claim 12, Stark suggests the use of statistical analysis and techniques (Stark: col 7, lns 41-48) but fails to explicitly disclose the specific statistical techniques of claim 12.

However, these features are well known in the art as evidenced by the teachings of Smith who discloses the method of determining subject compliance of claim 8, wherein

the step of generating employs at least one of the group of

multiple linear regression (Smith: Ch 15.)

discriminant function analysis,
logistic regression,
neural networks,

classification trees

and

regression trees.

It would have been obvious at the time of the invention to one of ordinary skill in the art to incorporate the teachings of Smith within the method of Stark with the motivation of isolating the separate effect of each of several independent variables on a single dependent variable (Smith: pg 620, second paragraph).

Response to Arguments

8. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches computerized methods of patient monitoring, including monitoring for treatment protocol compliance; as well as recruitment for and conducting clinical trials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN A. GOTTSCHALK whose telephone number is (571)272-7030. The examiner can normally be reached on Mon - Fri 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Dixon can be reached on (571) 272-6803. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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